IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SMITH KLINE & FRENCH LABORATORIES LIMITED and SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant	**PUBLIC VERSION** Civil Action No. 05-197-GMS

PLAINTIFF GLAXOSMITHKLINE'S OPPOSITION TO DEFENDANT'S MOTION *IN LIMINE* NO. 1 TO EXCLUDE EVIDENCE AND TESTIMONY ON COMMERCIAL SUCCESS

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October 30, 2006

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Teva's Motion To Exclude Evidence and Testimony On Commercial Success complains that GSK's expert on commercial success, as part of his expert analysis, ordered searches of third party market databases and that GSK produced the results of these searches as part of expert discovery, rather than fact discovery. Teva similarly complains that GSK's expert spoke with certain GSK employees, and that those employees were identified in his expert report, as opposed to during fact discovery. Teva's arguments incorrectly suggest that experts should be limited to data produced during fact discovery. Teva's motion should be denied.

1. Fact Discovery

During fact discovery, Teva served several overbroad requests purportedly directed to the issue of commercial success. For example, Teva's Document Request No. 51 sought "All Documents Concerning the . . . offer for sale or sale" of REQUIP®. Keller Aff., Ex. C. This

request alone, by encompassing every single sale of REQUIP (which has had more than $890 million in sales in the United States alone) is virtually boundless. Accordingly, GSK objected to such requests as overbroad. *Id.* GSK likewise objected that the issue of commercial success was properly the subject of expert discovery. *Id.* Nevertheless, rather than produce every piece of paper "concerning" every sale of REQUIP, GSK agreed to produce summary documents (namely "business plans, strategic plans, and marketing studies") and a compilation document "showing annual sales, costs (including costs for marketing and promotion), market share, profitability and price." *Id.* Even this production of summary documents was voluminous, resulting in (as Teva admits) more than 60,000 pages of documents. At no time did Teva request that GSK run queries in third party databases to generate additional sales information to produce during discovery. Nor did Teva ever complain about the adequacy of GSK's document production or discovery responses.

GSK also produced a knowledgeable fact witness on the subject of commercial success. In particular, in response to Teva's 30(b)(6) deposition notice, GSK produced Kevin Reeves, the Executive Brand Director for REQUIP. Among other things, Mr. Reeves authenticated and answered questions about the compilation document produced by GSK to show sales and marketing information since REQUIP's launch in 1997. Deposition of Kevin H. Reeves at 233:9 – 245:11 (Declaration of Mark L. Rienzi in Support of Plaintiff GlaxoSmithKline's Opposition to Defendant's Motion *In Limine* No. 1 to Exclude Evidence and Testimony on Commercial Success, Exhibit A).

REDACTED

REDACTED

Mr. Reeves explained that the compilation document was created by Mr. Jack Davis, a Vice President of Finance for GSK. Reeves Dep. at 235:3-9.

During Mr. Reeves' deposition, Teva also introduced more than 20 documents from GSK's production of sales and marketing documents, including many documents that discuss annual sales, market share, competition, and advertising and marketing expenditures. *See, e.g.*, Defendants' Exhibits 107-129.[1] Teva never complained about Mr. Reeves' adequacy as a 30(b)(6) witness on commercial success and did not seek to take Mr. Davis's deposition.

2. Expert Discovery

Under the Supreme Court's test for obviousness set forth in *Graham v. John Deere*, the commercial success of a patented product is one of the "objective indicia" or "secondary considerations" tending to show non-obviousness. *Graham v. John Deere*, 383 U.S. 1, 17 (1966). Accordingly, in response to Teva's claims of invalidity, GSK retained an expert economist, Dr. Christopher Vellturo, to provide an opinion as to the commercial success of REQUIP. After a careful review of the relevant data, Dr. Vellturo concluded

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It is not clear from Teva's expert reports and depositions how much of Dr. Vellturo's analysis is even being challenged.

REDACTED

[1] These documents correspond to Teva's trial exhibits 107-129. GSK can produce copies of these documents if the Court wishes to receive them.

REDACTED

As with any other expert report (and, indeed, *all* of Teva's expert reports) Dr. Vellturo's report cited to some documents produced during the litigation, and some that were not. As

[2] In fact, the FDA granted "priority review" to the application for approval to treat RLS. *See* http://www.fda.gov/cder/rdmt/ESCY05AP.htm (last accessed October 30, 2006). According to the FDA, the "priority review" designation is reserved for drugs that "if approved, would be a significant improvement compared to marketed products . . . in the treatment, diagnosis, or prevention of a disease." *See, e.g.*, http://www.fda.gov/cder/mapp/6020-3.pdf (last accessed October 30, 2006).

relevant here, in the course of preparing his expert report,

REDACTED

3. Argument

Teva's chief complaint is that Dr. Vellturo performed searches in third party databases while forming his expert opinion, but that those searches were not produced to Teva during fact discovery. Teva's position does not make sense: the data compilations generated in response to Dr. Vellturo's requests *did not exist until Dr. Vellturo asked for the searches*. Accordingly, they could not have been produced during fact discovery.

To the extent Teva's argument is that, because GSK subscribes to these databases, GSK should have produced to Teva *all* information about REQUIP sales in those databases, that argument is equally unfounded. Teva cites absolutely no authority for the proposition that its general discovery requests required GSK to search publicly available subscription data services to generate data to be produced. Teva's position is particularly unconvincing in light of the fact that

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Teva's complaint that "[i]ndeed, at substantial cost, Teva purchased its own third party data related to sales and marketing of Parkinson's drugs to respond to Dr. Vellturo," is particularly unconvincing. First, as stated above,

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Second, as required by Rule 26(a)(2)(B), GSK produced all of the data considered by Dr. Vellturo during expert discovery, Accordingly, there was no need for Teva to order this data anew.

Finally, Teva's arguments about Dr. Vellturo's conversations

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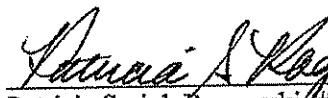
The conversations were disclosed in the report and were the subject of deposition questioning by Teva at Dr. Vellturo's deposition.

Conclusion

For these reasons, GSK respectfully requests that this Court deny Teva's motion.

SMITH KLINE & FRENCH LABORATORIES LIMITED AND SMITHKLINE BECHAM CORPORATION, D/B/A GLAXOSMITHKLINE
Respectfully submitted,



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Dated: October 30, 2006

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PROPOSED ORDER DENYING TEVA'S MOTION *IN LIMINE* NO. 1

The Court, having considered Defendant Teva's Pharmaceuticals USA Inc.'s ("Teva") Motion *In Limine* No. 1 to Exclude Evidence and Testimony On Commercial Success and the response of Plaintiff Smith Kline & French Laboratories Limited and SmithKline Beecham Corp, d/b/a/ GlaxoSmithKline ("GSK"), and all further arguments by the parties, hereby ORDERS this _____ day of _____, 2006 that Teva's Motion is DENIED.

_____

United States District Judge

CERTIFICATE OF SERVICE

I, Patricia Smink Rogowski, hereby certify that on November 6, 2006 **Public Version of Plaintiff GlaxoSmithKline's Opposition to Defendant's Motion In Limine No. 1 To Limit Evidence and Testimony on Commercial Success** was filed with the Court Clerk using CM/ECF which will send notification of such filing(s) to Josy W. Ingersoll.

I hereby further certify that on November 6, 2006, I have also served this document on the attorneys of record at the following addresses as indicated:

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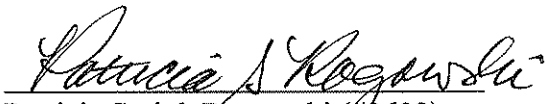

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